



Dexcom, Inc. | Corporate Headquarters
6340 Sequence Drive | San Diego, CA 92121
888.738.3646 | dexcom.com

Initiation of an Urgent: Medical Device Correction (see attachment) - Dexcom Non-Touchscreen Receiver:

I am writing to inform you that Dexcom has initiated a Medical Device Correction Notice (MDCN) for the Non-Touchscreen receiver. The following part numbers are impacted by this MDCN:

Table 1: Products Affected by this Field Action

Part Number	NDC/NRC Number	SKUs	Part Description
MT27408-1	08627-0091-11	STK-FM-001, STK-FR-001	Dexcom G6 Receiver
MT26403-0	08627-0078-01	STK-AT-011, STK-AT-012, STK-AT-013	Dexcom G7 Receiver

Background information and reason for the MDCN:

Dexcom recently became aware that users of the Non-Touchscreen receivers (SKUs listed above) may experience an issue where alarms/alerts may not function as designed. In such instances, the alarm/alert may not provide audio output when an audio prompt would be expected. A missed or delayed alarm/alert could potentially result in missed detection or treatment of severe hypoglycemia or hyperglycemia. Refer to Urgent Medical Device Correction Notification for additional details on Risk to Health. Dexcom has assessed that it is necessary to conduct an Urgent Medical Device correction to remind users to check their systems regularly in accordance with their instructions for use.

An impacted receiver will still provide an alert through vibration and visual prompts. Other receiver and system functions, including accuracy, are not impacted and there is no impact to Dexcom sensors or applications.

Required actions:

Please provide the MDCN to customers who have received product(s) listed in Table 1 via **one or more** of the following methods:

- Post the attached MDCN in a location in the pharmacy where it is visible to the public. Please keep the MDCN posted for a minimum of 3 months to promote awareness.
- Post the attached MDCN on the pharmacy website. Please keep the MDCN posted for a minimum of 3 months to promote awareness.
- Provide a print-out of the attached MDCN to customers when they fill a prescription for an affected Dexcom product
- Contact customers who have been sold affected product, to provide them with the MDCN

Dexcom will provide a list of affected lots that were shipped to your facility. We additionally request the following actions:

1. Screen inventory for affected lots
2. Quarantine affected product
3. Return affected product to wholesaler/distributor for replacement



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Should you have any questions regarding this letter, your obligations, or the MDCN, please reach out to your Dexcom Account contact.

Thank you for your help with this situation.

Sincerely,
Dexcom Quality Compliance



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Date: June 03, 2025

Urgent: Medical Device Correction UPDATE
Dexcom G6 Receiver – MT27408-1, Dexcom G7 Receiver – MT26403-0

Attention: Valued Dexcom Customer,

On May 12, 2025, Dexcom issued an Urgent Medical Device Correction notification concerning Dexcom receivers not providing audio output to alerts/alarms as expected. We are providing this updated notification to provide you with additional important safety information, and to help you identify if your Dexcom receiver may be impacted by this issue.

Details on Affected Devices:

This Urgent Medical Device Correction Update applies ONLY to users of Dexcom Receivers with a part number listed in Table 1 below. Users of a receiver with a part number listed in Table 1 should follow the *Recommended Customer Actions* to check the receiver serial number to find out if their receiver is affected by this issue. See Image 4 at the bottom of this notice for detail on where you can find the part number and serial number for your Receiver:

Table 1: Impacted Receiver Information - US

Part Number	SKUs	Part Description
MT27408-1	STK-FM-001, STK-FR-001	Dexcom G6 Receiver
MT26403-0	STK-AT-011, STK-AT-012, STK-AT-013	Dexcom G7 Receiver

Description of the Problem:

To date, users of the Dexcom G6 or G7 Receiver have reported an issue in which the receiver may not provide audio output to alerts/alarms as expected.

Note: An impacted receiver will still provide an alert through vibration and visual prompts. Other receiver and system functions, including accuracy, are not impacted.

Risk to Health:

If a user experiences a lack of receiver audio due to this issue, it may result in delayed and/or missed detection of severe hypoglycemia or hyperglycemia. Although a speaker test could identify a defective receiver, the malfunction can occur at any time without warning, even if the receiver has recently passed the speaker test. As of May 2025, 112 complaints have been received globally with confirmed association to this speaker malfunction. Globally, there have been 56 reports of severe adverse events (including seizure, loss of consciousness, vomiting, or unspecified hypoglycemic/hyperglycemic symptoms; all users recovered) potentially associated with this issue.

Recommended Customer Actions:

- Verify if your receiver is affected by this issue: Check the serial number for any receiver(s) you use, with a part number listed in Table 1, by visiting this webpage:
<https://dexcom.com/en-us/checkreceiver>
 - If you need assistance with the serial number verification process, please contact Dexcom Technical Support at 1-844-478-1600.
 - If your receiver is affected, contact Dexcom Technical Support at 1-844-478-1600 to coordinate return of the affected receiver and a no charge replacement.
- Whether or not your receiver is affected by this notification, Dexcom continues to recommend regular testing of the speaker. Test speaker function every time you charge your receiver. When you charge, a reminder prompt will invite you to test speaker function. See Reference Images 1-3 below.
 - Electively test the receiver speaker at any point through the menu:
Menu>Information>Receiver>Speaker>Test
 - If a speaker test is not successful, contact Dexcom Technical Support at 1-844-478-1600. If a speaker test is successful, continue to test speaker function regularly.

Contact reference information:

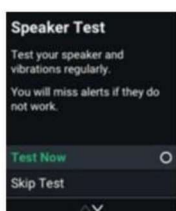
If you need assistance related to this issue or notification, please call **Dexcom Technical Support at 1-844-478-1600**. Technical Support is available 24 hours a day/7 days a week to assist you.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Reference Images:

**Image 1: Receiver
Speaker Test**



**Image 2: User Guide
Excerpt – G6**

Test Speaker and Vibrations
You have to hear or feel alarm/alerts to react to them, so test your receiver speaker and vibrations regularly.
To make sure the speaker and vibrations work, plug in the receiver to charge. The Speaker Test screen appears for a few seconds. Follow the directions on the screen to test the speaker and vibrations. If you hear and feel them, great! But if it doesn't beep and vibrate – perhaps it got wet or was dropped – contact Technical Support and use your app until the receiver is fixed.

**Image 3: User Guide
Excerpt – G7**

Test speaker and vibrations: Test your receiver speaker and vibrations regularly.
To make sure the speaker and vibrations work, plug in the receiver to charge. The Speaker Test screen appears for a few seconds. Follow the directions on the screen to test the speaker and vibrations. If it doesn't beep and vibrate, contact technical support and use your phone app, watch app, or BG meter until the receiver is fixed.

Image 4: Examples of Affected Receiver

- Note: The part number and serial number are both listed on the back of the receiver as shown in the image to the right/below):

Front of Receiver
Example Rendering:



Back of Receiver
Example Rendering:



On behalf of Dexcom, we apologize for any inconvenience this may cause.

Sincerely,
Dexcom Quality Compliance Team